IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF VIRGINIA
Norfolk Division

UNITED STATES OF AMERICA and the COMMONWEALTH OF VIRGINIA *ex rel.* ERIN CRAIG, *Plaintiffs*, v. SCOTT SAFFOLD, MD and CHESAPEAKE BAY ENT, P.C., *Defendants*.	Case No. 2:18-cv-435-RBS-LRL JURY TRIAL DEMANDED

THE UNITED STATES OF AMERICA'S AND THE COMMONWEALTH OF VIRGINIA'S COMPLAINT IN INTERVENTION

The United States of America and the Commonwealth of Virginia bring this action against the defendants, Chesapeake Bay ENT, P.C. (Chesapeake Bay) and its owner, Scott Saffold (Saffold) (collectively, the "Defendants"), for violations of the False Claims Act, 31 U.S.C. §§ 3729–33, the Virginia Fraud Against Taxpayers Act (VFATA), Va. Code §§ 8.01-216.1 *et seq.*, and the common law theories of fraud, unjust enrichment, and payment by mistake of fact resulting from false and/or fraudulent claims for payment that Saffold and Chesapeake Bay knowingly submitted to Medicare, Medicaid, and TRICARE for two types of medical procedures: (i) sphenoidoscopy procedures with punctures or cannulations that were not actually performed; and (ii) balloon dilation procedures that were not medically necessary and, in many cases, performed on separate days to increase the payment for the procedures, with no medical purpose, and while increasing the risk of harm to patients.

JURISDICTION AND VENUE

1. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1345 because this civil action arises under the laws of the United States and is brought by the United States pursuant to the False Claims Act.

2. The Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants can be found in and/or have transacted business within the Eastern District of Virginia.

3. The Court has jurisdiction over the Commonwealth of Virginia's VFATA and other state law claims pursuant to 31 U.S.C. § 3732(b) because the violations of state and federal law arise from the same transactions or occurrences as the action brought under 31 U.S.C. § 3730, as well as supplemental jurisdiction to entertain the state statutory, common, and equitable causes of action pursuant to 28 U.S.C. § 1367(a).

4. Venue is proper in the Eastern District of Virginia under 31 U.S.C. § 3732(a), 28 U.S.C. § 1391(b), and 28 U.S.C. § 1395(a) because the Defendants are located, reside, and do business in the Eastern District of Virginia, and the acts proscribed by 31 U.S.C. § 3729 occurred in this district.

PARTIES

5. Plaintiffs are the United States and the Commonwealth of Virginia.

6. The Virginia Attorney General brings this civil action in the name of the Commonwealth for damages resulting from false claims submitted to the Virginia Department of Medical Assistance Services (DMAS), the agency that administers the Virginia Medical Assistance Program (Virginia Medicaid) for the Commonwealth. The term "DMAS" includes,

and is interchangeable with, the Virginia Medicaid Program and any contractors or managed care organizations engaged by, or working on behalf of, DMAS or the Virginia Medicaid Program.

7. Defendant Chesapeake Bay, headquartered in Belle Haven, Virginia, specializes in the treatment of the ears, nose, throat, and related structures of the head and neck. Chesapeake Bay has seven locations in the Eastern District of Virginia.

8. Defendant Scott Saffold, residing in Virginia Beach, Virginia, is an otolaryngologist and an owner of Chesapeake Bay.

FEDERAL HEALTH CARE PROGRAMS

A. Medicare.

12. The United States, through the U.S. Department of Health and Human Services (HHS), administers the Medicare Program. HHS has delegated the administration of the Medicare Program to its component agency, the Centers for Medicare and Medicaid Services (CMS). The United States pays Medicare claims from the Medicare Trust Funds through CMS.

13. The Medicare program consists of four parts: A, B, C, and D. Medicare Part B covers, generally, physicians' services, outpatient care, durable medical equipment, preventative services, and certain physician-administered drugs. Medicare Part B covers the sphenoidoscopy and balloon dilation procedures that are the subject of this lawsuit.

14. At all times relevant to this complaint, CMS contracted with private contractors called "fiscal intermediaries," "carriers," and Medicare Administrative Contractors (MACs) to perform certain administrative functions on CMS's behalf.

15. Health care providers, including the Defendants, submit claims for services rendered to Medicare beneficiaries through fiscal intermediaries, carriers, and MACs for services rendered to Medicare beneficiaries.

16. The fiscal intermediaries, carriers, and MACs, on behalf of the United States, process and review Medicare claims submitted by health care providers and pay claims using federal funds.

17. To participate in the Medicare program, health care providers enter enrollment contracts with CMS in which the provider agrees to, among other things, satisfy all applicable statutory and regulatory requirements for Medicare payment, including certain provisions of Section 1862 of the Social Security Act and Title 42 of the Code of Federal Regulations.

18. Participating providers are prohibited from making false statements or misrepresentations of material facts concerning payment requests.

19. The most basic reimbursement requirement under Medicare is that the service or item provided must be reasonable and medically necessary.

20. Medicare does not cover items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

21. Healthcare providers must certify that services or items ordered or provided to patients will be provided economically and only when, and to the extent, medically necessary and will be of a quality which meets professionally recognized standards of health care and will be supported by evidence of medical necessity and quality.

22. Providers are prohibited from manipulating procedures in a wasteful manner to maximize their economic benefit while providing no patient benefit.

23. Requests for payment become false when they unreasonably and unnecessarily increase the services provided to patients without regard to medical necessity.

24. Providers who wish to be eligible to obtain Medicare reimbursement must certify that they agree to comply with the Medicare laws, regulations and program instructions that apply to them, and that they acknowledge that payment of claims by Medicare is conditioned upon the claim and the underlying transaction complying with all applicable laws, regulations, and program instructions.

25. Providers who wish to obtain reimbursement from Medicare also must be knowledgeable of, and abide by, all applicable Medicare statutes, regulations, and guidelines.

26. The Medicare rules and regulations that apply to providers, such as the Defendants, include:

a. Only bill Medicare for medically necessary products and services;

b. Do not make false statements or misrepresentations of material facts in connection with requests for payment;

c. Be able to provide evidence that the product or service given to the patient is medically necessary;

d. Make sure that products or services provided are not substantially in excess of the needs of the patient; and

e. Certify, when presenting a claim for reimbursement, that the service provided is a medical necessity.

B. Medicaid.

27. Medicaid provides federal grants to states for medical assistance to low-income, blind, or disabled persons, or to members of families with dependent children or qualified pregnant women or children.

28. The Medicaid program is jointly financed by the federal and state governments.

29. CMS administers Medicaid on the federal level.

30. The Commonwealth of Virginia is a Medicaid participating state, and, pursuant to Virginia law, the Virginia Medicaid program is administered by DMAS.

31. DMAS provides Medicaid services that are billed and reimbursed on a fee-for-service (FFS) basis and through managed care organizations (MCOs).

32. Federal and state regulations describe in detail the requirements of MCOs and providers participating in managed care plans that serve Medicaid beneficiaries.

33. MCOs contract with DMAS to offer Medicaid-covered services to their beneficiaries (in accordance with applicable regulations and the terms of the state contract), and providers in turn contract with the MCOs to deliver services to Medicaid beneficiaries.

34. Health care providers, including the Defendants, submit claims for services rendered to Medicaid beneficiaries to DMAS or MCOs for payment in connection services rendered to Virginia Medicaid Program beneficiaries.

35. Claims that health care providers, including the Defendants, submit to DMAS or MCOs for payment in connection with services provided to Virginia Medicaid Program beneficiaries are paid through funds provided by the United States and the Virginia Medicaid Program

36. To enroll in the Virginia Medicaid program, a provider must execute a participation agreement with DMAS.

37. By executing a participation agreement, the provider agrees to adhere to the policies and regulations contained in the manuals pertaining to the specific services provided, including documentation requirements, necessary qualifications for staff, and rules for billing DMAS. The provider also agrees to comply with all applicable state and federal laws.

38. The Virginia Medicaid program provider participation agreement requires that medical records fully disclose the extent of services provided to all Medicaid members.

39. Medical records must clearly document the medical necessity for covered services.

40. Documentation for each service must be created at the time the service is rendered and the description of the services rendered must be clear. All documentation must be signed, with name and title, and dated on the date that services are delivered.

C. TRICARE.

41. TRICARE provides health care for U.S. servicemembers, retirees, and their families, among other eligible individuals.

42. TRICARE is administered by the U.S. Department of Defense's Defense Health Agency.

43. The funds used by TRICARE to pay medical claims of qualified individuals are funds appropriated by the United States.

44. TRICARE primarily processes claims from civilian providers through Managed Care Support Contractors (MCSCs) or WPS Health Solutions (WPS), a private claims processing business.

45. MCSCs negotiate agreements with civilian sector health care providers, which are known as "network agreements."

46. Humana Military was the MCSC for the TRICARE North Region and is now the MCSC for the TRICARE East Region, which includes the Commonwealth of Virginia.

47. Humana Military subcontracted with PGBA, LLC for the TRICARE North Region and WPS for the TRICARE East Region to receive and process claims from civilian providers on behalf of TRICARE.

48. Health care providers, including the Defendants, submit claims for services rendered to TRICARE beneficiaries to WPS for payment in connection services rendered to TRICARE beneficiaries.

49. Claims that health care providers, including the Defendants, submit to WPS for payment in connection with services provided to TRICARE beneficiaries are paid with funds provided by the United States.

50. Providers are required to provide services and supplies at the appropriate level and only when and to the extent medically necessary.

51. Providers are required to support their claims with adequate medical documentation to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care.

THE CLAIM SUBMISSION PROCESS

52. Health care providers, including the Defendants, submit claims for payment to Medicare, Medicaid, and TRICARE using CMS Form 1500, "Health Insurance Claim Form," or its electronic equivalent.

53. Five-digit codes, known as Current Procedural Terminology (CPT) codes, identify the services rendered and for which reimbursement is sought.

54. CPT codes, including the services that must be provided in connection with each code, are published by the American Medical Association (AMA) in the AMA CPT Codebook.

55. The health care provider is required to list a CPT code or Healthcare Common Procedure Coding System code on the CMS Form 1500 in connection with each procedure for which the health care provider is seeking payment. The claims at issue in this case were submitted using CPT codes.

56. The CMS Form 1500 requires the health care provider, in submitting a claim for payment from federal funds, to certify that: 1) the information on the form is true, accurate and complete; 2) the provider familiarized herself with all applicable laws, regulations, and program instructions, which are available from the Medicare contractor; 3) the provider has provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) the claim, whether submitted by the provider or on her behalf by a designated billing company, complies with all applicable laws, regulations, and program instructions for payment; and 5) the services claimed on the form were medically necessary.

FACTS

57. From at least January 1, 2012, to at least August 29, 2019, Chesapeake Bay and Saffold knowingly engaged in a scheme to submit fraudulent claims to obtain payments from federal health care payors, including Medicare, Medicaid, and TRICARE, for sphenoidoscopy procedures with punctures or cannulations that were not actually performed by Saffold or physician assistants under his supervision.

58. Separately and in addition, since at least January 1, 2012, Chesapeake Bay and Saffold knowingly engaged in a scheme to submit fraudulent claims to obtain payments from federal health care payors, including Medicare, Medicaid, and TRICARE, for balloon dilation procedures that were not medically necessary for their patients and in many cases were

performed on separate days to increase the payment for the procedures, with no medical purpose, and while increasing the risk of harm to the patients.

I. The Defendants Submitted False Claims for Sphenoidoscopy Procedures with Punctures or Cannulations that were not Performed.

59. Sphenoidoscopy, also known as sphenoid sinusoscopy, is a diagnostic procedure by which a provider inserts an endoscope, a small instrument containing an image sensor or optical lens, through the nasal cavity and into one of the sphenoid sinuses, located at the back of the nasal passage at eye level, to evaluate the anatomy of the patient's sinus and diagnose conditions affecting the sinus.

60. Depending on the patient's condition and the structure of the patient's nasal and sinus passages, the sphenoidoscopy procedure may require intervention to create an opening or enlarge the natural opening to allow the physician to insert the endoscope into the patient's sphenoid sinus.

61. In such cases, the provider can create an opening for the endoscope by puncturing the patient's sphenoid face, i.e., the font/anterior wall of the sphenoid sinus, with a sharp instrument to forcibly twist and push through the bone of the sphenoid face, or by cannulating the patient's ostium, i.e., the opening to the sphenoid sinus, with instruments such as a trocar, surgical elevator, or angulated forceps to dilate and enlarge the natural opening.

62. The AMA provides a series of CPT codes for diagnostic sinus endoscopy that vary based on whether (a) the endoscope was inserted through an existing opening, such as through the nasal cavity or a passage previously created through surgery, or (b) the surgeon had to create an opening large enough for the endoscope by puncturing the sphenoid face or cannulating the ostium.

63. CPT code 31231 is defined as nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure).

64. CPT code 31231 provides a flat reimbursement rate for examining both sides of the nasal cavity.

65. CPT code 31235 is defined as nasal/sinus endoscopy, diagnostic with sphenoid sinusoscopy (via puncture of sphenoidal face or cannulation of ostium).

66. CPT code 31235 allows the provider to bill for performing the procedure on only one of the patient's sphenoid sinuses, and it provides for increased reimbursement when the procedure is performed bilaterally, i.e., on both of the patient's sphenoid sinuses.

67. To qualify for payment under CPT code 31235, the surgeon must puncture the patient's sphenoidal face or cannulate the patient's ostium prior to placing the diagnostic scope into the patient's sphenoid sinus.

68. CPT code 31235 provides for higher reimbursement rates than the reimbursement rates for sphenoidoscopy procedures that do not require the creation of an entryway through puncture or cannulation, which must be billed under CPT code 31231.

69. CPT code 31235 also provides for higher reimbursement rates than CPT code 31231 because CPT code 31235 can be billed bilaterally, meaning the provider receives a higher payment when the procedure is performed on both of the patient's sphenoid sinuses.

70. CPT code 31235 cannot be used for sphenoidoscopy procedures when the endoscope is inserted through a preexisting opening, such as an opening created during a prior sphenoidoscopy procedure with puncture or cannulation or a prior sphenoid sinusotomy procedure, during which the surgeon creates a permanent opening in the patient's sphenoid sinus.

71. CPT code 31235 cannot be used for procedures that do not include inserting an endoscope into the patient's sphenoid sinus.

72. From at least January 1, 2012 to at least August 29, 2019, the Defendants routinely submitted false and fraudulent claims to Medicare, Medicaid, and TRICARE for reimbursement under CPT code 31235, even though the procedures did not qualify for claims under CPT code 31235 because the procedures did not include and/or did not require puncturing the patient's sphenoidal face or cannulating the patient's sphenoid ostium.

73. In each of these claims that the Defendants submitted to the United States, the Defendants falsely certified that the procedure met the requirements for reimbursement under CPT code 31235.

74. The medical records for each of these claims do not indicate that a puncture or cannulation was performed as required to submit a claim for CPT code 31235.

75. Certain medical records for procedures that the Defendants billed as CPT code 31235 state that the sphenoid was entered through a sphenoidotomy, i.e., a sufficient opening into the sphenoid created during a prior surgical procedure, further establishing that no puncture or cannulation was performed on the date of service as required to submit a claim for CPT code 31235.

76. Other medical records for procedures that the Defendants billed as CPT code 31235 state that the sphenoid was not visualized or entered, in which case the sphenoid was not examined—nor punctured, nor cannulated—as required to submit a claim for CPT code 31235.

77. Saffold knew the United States would not pay a claim for CPT code 31235 unless the sphenoidoscopy procedure involved a puncture or cannulation based on the plain language of

the AMA's definition of CPT code 31235 and generally accepted medical practices for performing procedures associated with CPT code 31235.

78. Saffold knew the claims for CPT code 31235 were false because he, and physician assistants acting under Saffold's supervision, performed the procedures without a puncturing or cannulation.

79. Saffold and the physicians acting under his supervision performed the procedures on behalf of and for the benefit of Chesapeake Bay.

80. Saffold and Chesapeake Bay knew claims for CPT code 31235 required puncture or cannulation based on the plain language of the CPT code's definition and generally accepted medical practices involving ear, nose, and throat procedures.

81. Saffold and Chesapeake Bay knew that CPT code 31231 was the appropriate CPT code for reimbursement for sphenoidoscopy procedures where a puncture or cannulation was not performed or necessary to reach the patient's sphenoid with an endoscope.

82. Saffold and Chesapeake Bay fraudulently submitted claims for CPT code 31235, and instead of CPT code 31231, because CPT code 31235 provided for higher reimbursement than CPT code 31231.

83. Saffold and Chesapeake Bay fraudulently submitted claims for CPT code 31235 because CPT code 31235 allowed Saffold and Chesapeake Bay to bill for more procedures than if Saffold and Chesapeake Bay submitted claims for CPT code 31231, which only allows the provider to submit one claim for examining both sides of the nasal cavity.

84. If Medicare, Medicaid, or TRICARE knew that the procedures for which Saffold and Chesapeake Bay submitted claims for CPT code 31235 did not include puncture or cannulation, and an examination of the sphenoid sinus, then the claims would have been denied.

85. But for the Defendants' certifications that the procedures qualified for reimbursement under CPT code 31235, Medicare, Medicaid, and TRICARE would not have paid the Defendants for their claims.

86. The following paragraphs contain demonstrative examples of false claims that the Defendants knowingly submitted for payment under CPT code 31235.

A. Patient M.S.

87. In September 2013, patient M.S. underwent bilateral sphenoidotomies, which created a permanent opening in his sphenoid sinuses.

88. After M.S. underwent the bilateral sphenoidotomies, Saffold submitted, or caused to be submitted, claims to Medicare using CPT code 31235 for subsequent sphenoidoscopy procedures on patient M.S., even though neither Saffold nor the physician assistants acting under his supervision performed punctures or cannulations during those procedures.

89. The following table lists the dates of service, claim submission date, and amount Medicare paid in connection with a non-exhaustive list of claims for which the Defendants knowingly submitted fraudulent claims for CPT code 31235 for services rendered to patient M.S. that did not satisfy the requirements for billing under CPT code 31235:

Row	Claim Date of Service	Claim Submission Date	Medicare Paid
1	October 3, 2013	October 4, 2013	$ 352.66
2	October 15, 2013	October 21, 2013	$ 352.66
3	November 26, 2013	December 3, 2013	$ 352.66
4	December 31, 2013	January 3, 2014	$ 352.66
5	January 21, 2014	January 23, 2014	$ 345.45
6	January 30, 2014	January 31, 2014	$ 345.45
7	February 13, 2014	February 17, 2014	$ 345.45
8	February 27, 2014	March 3, 2014	$ 345.45
9	May 29, 2014	June 2, 2014	$ 345.45
10	November 20, 2014	January 29, 2015	$ 345.45
11	January 8, 2015	January 29, 2015	$ 231.13
12	March 12, 2015	August 17, 2015	$ 231.13

Row	Claim Date of Service	Claim Submission Date	Medicare Paid
	Total Amount Paid		**$ 3,945.60**

90. In each of procedures for which the Defendants sought payment through the claims identified in paragraph 89, neither Saffold nor physician assistants acting under his supervision punctured the sphenoid face or cannulated the ostium.

91. The medical records associated with each of the claims identified in Rows 1–4, 6–9, and 11–12 of paragraph 89 expressly state that one of patient M.S.'s sphenoids was entered through the sphenoidotomy, which was performed in September 2013, further establishing that no puncture or cannulation was performed as required by CPT code 31235.

92. Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to Medicare seeking payment for the procedures identified in paragraph 89 using CPT code 31235.

93. Saffold and Chesapeake Bay knew that the claims for the procedures identified in paragraph 89 did not qualify for CPT code 31235 because they knew none of the procedures included puncture or cannulation, which they knew was required by the express language of CPT code 31235.

94. Based on Saffold's and Chesapeake Bay's false representations about the services rendered to patient M.S. in the claims identified in paragraph 89, Medicare paid Chesapeake Bay $3,945.60.

95. Medicare would not have paid for the procedures identified in paragraph 89 if Medicare had known they did not include puncturing the sphenoid face or cannulating the ostium.

96. The Defendants submitted the claims identified in paragraph 89 for CPT code 31235 instead of CPT code 31231, which does not require puncture or cannulation, to obtain higher payments from Medicare.

B. Patient C.H.

97. On March 12, 2012, patient C.H. underwent functional endoscopic sinus surgery, which created permanent openings in her sphenoid sinuses.

98. After patient C.H. underwent functional endoscopic sinus surgery, Saffold submitted claims to Medicare using CPT code 31235 for subsequent diagnostic procedures on patient C.H., even though Saffold did not perform punctures or cannulations as required for payment under CPT code 31235.

99. The following table lists the dates of service, claim submission date, and amount Medicare paid in connection with a non-exhaustive list of claims for which the Defendants knowingly submitted fraudulent claims for CPT code 31235 for services rendered to patient C.H that did not satisfy the requirements for billing under CPT code 31235:

Row	Claim Date of Service	Claim Submission Date	Medicare Paid
1	April 10, 2012	April 14, 2012	$ 355.91
2	April 17, 2012	April 18, 2012	$ 355.91
3	May 15, 2012	May 16, 2012	$ 355.91
4	June 12, 2012	June 13, 2012	$ 355.91
5	June 26, 2012	June 28, 2012	$ 355.91
6	July 19, 2012	July 25, 2012	$ 355.91
7	August 9, 2012	August 16, 2012	$ 237.27
8	August 16, 2012	August 17, 2012	$ 355.91
9	August 23, 2012	August 27, 2012	$ 355.91
10	August 30, 2012	September 5, 2012	$ 355.91
11	September 6, 2012	September 11, 2012	$ 237.27
12	September 13, 2012	September 19, 2012	$ 355.91
13	September 27, 2012	October 8, 2012	$ 355.91
14	November 1, 2012	November 2, 2012	$ 355.91
15	November 29, 2012	December 1, 2012	$ 355.91

Row	Claim Date of Service	Claim Submission Date	Medicare Paid
16	January 31, 2013	February 5, 2013	$ 283.82
17	February 14, 2013	February 15, 2013	$ 359.86
18	April 2, 2013	April 8, 2013	$ 352.66
19	April 11, 2013	April 19, 2013	$ 352.66
20	May 2, 2013	May 3, 2013	$ 352.66
21	June 13, 2013	June 18, 2013	$ 352.66
22	September 17, 2013	September 23, 2013	$ 352.66
23	December 19, 2013	December 19, 2013	$ 352.66
24	January 2, 2014	January 3, 2014	$ 237.97
25	January 16, 2014	January 20, 2014	$ 345.45
26	January 28, 2014	January 31, 2014	$ 345.45
27	July 3, 2014	July 8, 2014	$ 345.45
28	July 17, 2014	July 28, 2014	$ 345.45
29	September 9, 2014	September 26, 2014	$ 345.45
30	October 2, 2014	October 4, 2014	$ 345.45
31	October 28, 2014	October 30, 2014	$ 345.45
32	December 4, 2014	December 19, 2014	$ 345.45
33	January 6, 2015	January 16, 2015	$ 272.72
34	January 27, 2015	February 3, 2015	$ 346.70
35	March 19, 2015	May 29, 2015	$ 346.70
36	April 2, 2015	May 29, 2015	$ 346.70
37	June 4, 2015	June 10, 2015	$ 346.70
38	June 25, 2015	June 26, 2015	$ 346.70
39	October 8, 2015	October 16, 2015	$ 348.44
40	November 5, 2015	November 10, 2015	$ 348.44
41	February 4, 2016	February 17, 2016	$ 347.06
42	March 16, 2016	March 16, 2016	$ 347.06
43	April 7, 2016	April 29, 2016	$ 347.06
44	May 12, 2016	May 20, 2016	$ 347.06
45	August 11, 2016	December 28, 2016	$ 347.06
46	November 10, 2016	November 15, 2016	$ 347.06
47	March 2, 2017	June 7, 2017	$ 338.04
48	February 22, 2018	April 27, 2018	$ 350.21
	Total Amount Paid		**$ 16,336.29**

100. In each of procedures for which the Defendants sought payment through the claims identified in paragraph 99, neither Saffold nor physician assistants acting under his supervision punctured the sphenoid face or cannulated the ostium.

101. The medical records associated with the claims identified in Rows 2–5, 7–23, 28–41, 43–46, and 48 of paragraph 99 expressly state that one of patient C.H.'s sphenoids was entered through a sphenoidotomy, further establishing that no puncture or cannulation was performed as required by CPT code 31235.

102. Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to Medicare seeking payment for the procedures identified in paragraph 99 using CPT code 31235.

103. In each of the claims identified in paragraph 99, the Defendants falsely represented that the services rendered were properly described as CPT code 31235, even though the procedures did not qualify for payment under CPT code 31235.

104. Saffold and Chesapeake Bay knew that the claims for the procedures identified in paragraph 99 did not qualify for CPT code 31235 because they knew that none of the procedures included puncture or cannulation, which they knew was required by the express language of CPT code 31235.

105. Based on the Defendants' false representations in each of the claims for payment identified in paragraph 99, Medicare paid Chesapeake Bay $16,336.29.

106. Medicare would not have paid for the claims identified in paragraph 99 if Medicare had known they did not include puncturing the sphenoid face or cannulating the ostium.

107. The Defendants submitted the claims identified in paragraph 99 for CPT code 31235 instead of CPT code 31231, which does not require puncture or cannulation, to obtain higher payments from Medicare.

C. Patient D.G.

108. Saffold and Chesapeake Bay billed CPT code 31235 for procedures performed on patient D.G. even when the physician assistant acting under Saffold's supervision did not examine the inside of the patient's sphenoid sinuses, let alone perform a puncture or cannulation to conduct the examination.

109. Patient D.G. had undergone prior sphenoidotomies, after which the Defendants submitted a series of fraudulent claims for endoscopy procedures using CPT code 31235 that did not include punctures or cannulations.

110. On August 14, 2013, October 16, 2013, and October 13, 2015, a physician assistant acting under Saffold's supervision was not able to visualize and/or enter patient C.W.'s sphenoid sinuses to conduct an examination.

111. The physician assistant did not puncture or cannulate the patient's sphenoid sinuses during any of these procedures.

112. Because the sphenoid sinuses were not examined, and no puncture or cannulation was performed, the procedures did not qualify for payment under CPT code 31235.

113. The physician assistant, acting under Saffold's supervision and on behalf of Chesapeake Bay, knew she had not conducted sphenoidoscopy procedures with puncture or cannulation on August 14, 2013, October 16, 2013, and October 13, 2015 because she did not even enter patient C.W.'s sphenoid sinuses to conduct the examination.

114. Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to Medicaid seeking payment for these procedures using CPT code 31235.

115. In the each of these claims, the Defendants falsely represented that the services rendered were properly described as CPT code 31235.

116. The Defendants knew that these procedures were false because they knew they did not examine the sphenoid by puncture or cannulation, which they knew was required by the express language of CPT code 31235.

117. Based on the Defendants' false representations in their claims for payment, Medicaid paid $404.60 in connection with the August 14, 2013 endoscopy for patient D.G., $416.60 in connection with the October 16, 2013 endoscopy for patient D.G., and $412.47 for the October 13, 2015 endoscopy for patient D.G.

118. Medicaid would not have paid for these procedures if Medicare had known they did not include puncturing the sphenoid face or cannulating the ostium.

119. The Defendants submitted these claims for CPT code 31235 instead of CPT code 31231 to obtain higher payments from Medicaid.

II. The Defendants' Submission of False Claims for Medically Unnecessary Balloon Dilation Procedures.

120. Balloon dilation is a surgery in which a doctor directs a balloon through the nasal passageways into the ostium of a sinus cavity and then inflates the balloon to enlarge the sinus opening.

121. During the relevant period, the Defendants submitted CMS Form 1500s seeking reimbursement from Federal and State health care payors for balloon dilation procedures using CPT codes 31295, 31296, 31297, and 31298.

122. CPT code 31295 is defined as nasal/sinus endoscopy, surgical; with dilation of maxillary sinus ostium (e.g., balloon dilation), transnasal or via canine fossa. This CPT code is

used for balloon dilation procedures on the ostium of one of the maxillary sinuses, which are below the eyes in the cheek bone.

123. CPT code 31296 is defined as dilation of frontal sinus ostium (e.g., balloon dilation). This CPT code is used for balloon dilation procedures conducted on the ostium of one of the frontal sinuses, which are near the tops of the eyes and into the forehead.

124. CPT code 31927 is defined as dilation of sphenoid sinus ostium (e.g., balloon dilation). This CPT code is used for balloon dilation procedures conducted on the ostium of one of the sphenoid sinuses, which are at the back of the nasal passage at eye level.

125. CPT Code 31928 is defined as nasal/sinus endoscopy, surgical, with dilation (eg, balloon dilation); frontal and sphenoid sinus ostia. This CPT code was implemented in January 2018 to bundle claims for CPT codes 31296 and 31297.

126. To identify whether the balloon dilation procedure was performed on the left or right side of the patient's nasal passage, the physician adds a modifier to the claim in the Form 1500.

127. Sinusitis, also known as a sinus infection, causes patients to experience inflammation or swelling in one or more sinuses, which restricts the sinus cavity and causes the sinus to fill with fluid, leading to sinus pressure and nasal congestion.

128. Balloon dilation is used to treat chronic or recurring sinusitis, which is defined as inflammation or swelling of the sinus lasting three or more months, or recurrent acute sinusitis, which is defined as four or more sinus infections per year.

129. To determine whether balloon dilation is medically necessary for a specific patient, a physician is to perform a physical exam and evaluation, which may include an

endoscopy and/or a CT scan, and which allows the physician to evaluate which sinuses are exhibiting sinusitis and to what extent.

130. After the physical exam, the physician orders a course of treatment, beginning with non-surgical treatment including antibiotics, nasal sprays, and steroids, and only moving to surgical interventions if the non-surgical treatments are unsuccessful.

131. If, upon further evaluation, one or more of the patient's sinuses remain diseased, then balloon dilation could be medically necessary to treat each diseased sinus.

132. Sinuses that do not exhibit signs of sinusitis are not eligible for reimbursement for balloon dilation because the procedure is not medically necessary.

133. During balloon dilation, the surgeon inserts the balloon into the cavity of one of the patient's six sinuses for which the procedure can be utilized.

134. The surgeon then inflates the balloon, which enlarges the patient's sinus and allows the sinus to drain or provide better air exchange, thereby relieving the symptoms associated with the patient's sinusitis.

135. The surgeon completes the procedure by deflating and removing the balloon from the patient's sinus.

136. Patients typically experience discomfort in the nasal area and continued drainage in the days following the procedure.

137. Following the procedures, the health care provider submits claims for reimbursement listing the sinuses for which the provider performed a balloon dilation.

138. Since at least January 1, 2012, Saffold routinely performed balloon dilation procedures on patients that were not medically necessary to fraudulently obtain payments from Medicare, Medicaid, and TRICARE.

139. Specifically, Saffold, as the rendering physician and on behalf of Chesapeake Bay, performed balloon dilation procedures on patients who, according to their medical records and/or diagnostic evaluations, did not exhibit symptoms of sinusitis in each of the sinuses for which Saffold performed the procedure.

140. Because these patients did not exhibit sinusitis in the dilated sinuses, the balloon dilations performed by Saffold were not medically necessary.

141. Even though the balloon dilations were not medically necessary, the Defendants submitted claims for payment in which they falsely certified the balloon dilations were medically necessary.

142. Saffold knew these claims were not medically necessary because, as the rendering provider, Saffold knew that the patients did not exhibit sinusitis in the dilated sinuses, so a balloon dilation was not medically necessary.

143. Based on the Defendants' false certifications, the Government paid the Defendants for the medically unnecessary balloon dilations.

144. In addition, Saffold performed the balloon dilations as staged procedures, meaning that, rather than perform balloon dilation procedures on the left sinuses and the right sinuses on the same day, he performed the procedures on one side on one day, and the other side on another day, in order to increase the amount Chesapeake Bay would be reimbursed for these procedures.

145. If Saffold performed the balloon dilation procedures on the left and right sinuses on the same day, the claims for reimbursement would have included a bilateral modifier that reduced the overall payment amount.

146. There is no medical benefit to staging these procedures and staging the procedures can create a greater risk of infection and a greater risk of side effects from the medications prescribed in connection with the balloon dilations since staging the procedures results in the medications being prescribed twice.

147. The following paragraphs contain demonstrative examples of false claims that the Defendants knowingly submitted for payment for medically unnecessary balloon dilation procedures.

A. Patient C.W.

148. On August 11, 2016, Saffold performed three balloon dilation procedures on patient C.W.'s right maxillary, frontal, and sphenoid sinuses.

149. On August 18, 2016, Saffold performed three more balloon dilation procedures on patient C.W.'s left maxillary, frontal, and sphenoid sinuses.

150. Prior to these balloon dilation procedures, on July 7, 2016, patient C.W. underwent a CT scan that showed no mucosal thickening in any of patient C.W.'s sinuses, which meant Patient C.W.'s sinuses were not blocked.

151. The six balloon dilation procedures, conducted on August 11 and 18, 2016, were not medically necessary and reasonable services because the procedures were not appropriate for patient C.W.'s condition.

152. Specifically, the six balloon dilation procedures conducted on patient C.W.'s sinuses were not furnished in accordance with accepted standards of medical practice for the treatment of patient C.W.'s condition, and they exceeded patient C.W.'s medical need.

153. Saffold knew these balloon dilation procedures were medically unnecessary because he reviewed patient C.W.'s CT scan, which showed no blockage.

154. Saffold also staged these procedures, even though there was no medical benefit to staging them, and staging the procedures increased the risk of harm to the patient.

155. On August 26, 2016, Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to TRICARE seeking payment for the three balloon dilation procedures conducted on patient C.W.'s sinuses on August 11, 2016, using CPT codes 31295, 31296, and 31297, with a modifier indicating the procedures had been performed on the right side.

156. On August 30, 2016, Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to TRICARE seeking payment for the three balloon dilation procedures conducted on patient C.W.'s sinuses on August 18, 2016, using CPT codes 31295, 31296, and 31297, with a modifier indicating the procedures had been performed on the left side.

157. In the claims, the Defendants falsely represented that the balloon dilation procedures conducted on August 11 and 18, 2016, were medically necessary to treat patient C.W.'s condition.

158. Based on the Defendants' false representations in their claims for payment, TRICARE paid $7,851 for the six medically unnecessary balloon dilation procedures that Saffold performed on August 11 and 18, 2016.

159. TRICARE would not have paid for these procedures if TRICARE had known they were medically unnecessary.

B. Patient D.B.

160. On November 24, 2015, Saffold performed three balloon dilation procedures on patient D.B.'s left maxillary, frontal, and sphenoid sinuses.

161. On December 2, 2015, Saffold performed three more balloon dilation procedures on Patient D.B.'s right maxillary, frontal, and sphenoid sinuses.

162. On October 19, 2015, patient D.B. underwent a CT scan that showed no sinus disease in any of patient D.B.'s sinuses, which meant patient D.B.'s sinuses were not blocked.

163. The six balloon dilation procedures, conducted on November 24, and December 2, 2015, were not medically necessary and reasonable services because the procedures were not appropriate for patient D.B.'s condition.

164. Specifically, the six balloon dilation procedures conducted on patient D.B.'s sinuses were not furnished in accordance with accepted standards of medical practice for the treatment of patient D.B.'s condition, and they exceeded patient D.B.'s medical need.

165. Saffold knew these balloon dilation procedures were medically unnecessary because he reviewed patient D.B.'s CT scan, which showed no blockage.

166. Saffold also staged these procedures, even though there was no medical benefit to staging them, and staging the procedures increased the risk of harm to the patient.

167. On November 25, 2015, Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to Medicare and TRICARE seeking payment for the three balloon dilation procedures conducted on patient D.B.'s sinuses on November 24, 2015, using CPT codes 31295, 31296, and 31297, with a modifier indicating the procedures had been performed on the left side.

168. On December 3, 2015, Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to Medicare and TRICARE seeking payment for the three balloon dilation procedures conducted on patient D.B.'s sinuses on

December 2, 2015, using CPT codes 31295, 31296, and 31297, with a modifier indicating the procedures had been performed on the right side.

169. In the claims, Defendants falsely represented that the balloon dilation procedures conducted on November 24, and December 2, 2015, were medically necessary to treat patient D.B.'s condition.

170. Based on the Defendants' false representations in their claims for payment, Medicare paid $6,404.64 for the six medically unnecessary balloon dilation procedures that Saffold performed on November 24, and December 2, 2015.

171. Medicare would not have paid for these procedures if Medicare had known they were medically unnecessary.

172. Based on the Defendants' false representations in their claims for payment, TRICARE also paid $1,633.82 as a secondary payor for the six medically unnecessary balloon dilation procedures that Saffold performed on November 24, and December 2, 2015.

173. TRICARE would not have paid for these procedures if TRICARE had known they were medically unnecessary.

C. Patient R.W.

174. On September 26, 2016, Saffold performed three balloon dilation procedures on patient R.W.'s left maxillary, frontal, and sphenoid sinuses.

175. On October 3, 2016, Saffold performed three more balloon dilation procedures on patient R.W.'s right maxillary, frontal, and sphenoid sinuses.

176. On July 6, 2016, patient R.W. underwent a CT scan that showed only minimal thickening in only patient R.W.'s maxillary sinus, which meant patient R.W.'s frontal and sphenoid sinuses were not blocked.

177. Four of the six balloon dilation procedures, conducted on September 26 and October 3, 2016, were not medically necessary and reasonable services because the procedures were not appropriate for patient R.W.'s condition.

178. Specifically, four of the six balloon dilation procedures conducted on patient R.W.'s sinuses were not furnished in accordance with accepted standards of medical practice for the treatment of patient R.W.'s condition, and they exceeded patient R.W.'s medical need.

179. Saffold knew these balloon dilation procedures were medically unnecessary because he reviewed patient R.W's CT scan, which showed no blockage in four of the six sinuses.

180. On October 28, 2016, Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to TRICARE seeking payment for the three balloon dilation procedures conducted on patient R.W.'s sinuses on September 26, 2016, using CPT codes 31295, 31296, and 31297, with a modifier indicating the procedures had been performed on the left side.

181. On November 17, 2016, Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to TRICARE seeking payment for the three balloon dilation procedures conducted on patient R.W.'s sinuses on October 3, 2016, using CPT codes 31295, 31296, and 31297, with a modifier indicating the procedures had been performed on the right side.

182. In the claims, the Defendants falsely represented that all six balloon dilation procedures conducted on September 26 and October 3, 2016, were medically necessary to treat patient R.W.'s condition, but the four procedures billed under CPT codes 31296 and 31297 were not medically necessary.

183. Based on the Defendants' false representations in their claims for payment, TRICARE paid $4,683.12 for the four medically unnecessary balloon dilation procedures that Saffold performed on September 26 and October 3, 2016.

184. TRICARE would not have paid for these procedures if TRICARE had known they were medically unnecessary.

D. Patient P.J.

185. On April 29, 2015, Saffold performed three balloon dilation procedures on patient P.J.'s left maxillary, frontal, and sphenoid sinuses.

186. On May 6, 2015, Saffold performed three more balloon dilation procedures on patient P.J.'s right maxillary, frontal, and sphenoid sinuses.

187. On January 27, 2015, patient P.J. underwent a CT scan that showed layered fluid in only P.J.'s maxillary sinuses, which meant patient P.J.'s frontal and sphenoid sinuses were not blocked.

188. Four of the six balloon dilation procedures, conducted on April 29 and May 6, 2015, were not medically necessary and reasonable services because the procedures were not appropriate for patient P.J.'s condition.

189. Specifically, four of the six balloon dilation procedures conducted on patient P.J.'s sinuses were not furnished in accordance with accepted standards of medical practice for the treatment of patient P.J.'s condition, and they exceeded patient P.J.'s medical need.

190. Saffold knew these balloon dilation procedures were medically unnecessary because he reviewed Patient P.J's CT scan, which showed no blockage in four of the six sinuses.

191. Saffold also staged these procedures, even though there was no medical benefit to staging them, and staging the procedures increased the risk of harm to the patient.

192. On May 6, 2015, Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted claims using Form 1500 to Medicare seeking payment for the three balloon dilation procedures conducted on patient P.J.'s sinuses on April 29, 2015, using CPT codes 31295, 31296, and 31297, with a modifier indicating the procedures had been performed on the left side.

193. On May 6, 2015, Saffold submitted, or caused to be submitted, and Chesapeake Bay submitted also submitted claims using Form 1500 to Medicare seeking payment for the three balloon dilation procedures conducted on patient P.J.'s sinuses on May 6, 2015, using CPT codes 31295, 31296, and 31297, with a modifier indicating the procedures had been performed on the right side.

194. In the claims, the Defendants falsely represented that all six balloon dilation procedures conducted on September 26 and October 3, 2016, were medically necessary to treat patient P.J.'s condition, but the four procedures billed under CPT codes 21296 and 31297 were not medically necessary.

195. Based on the Defendants' false representations in their claims for payment, Medicare paid $4,789 for the four medically unnecessary balloon dilation procedures that Saffold performed on April 29 and May 6, 2015.

196. Medicare would not have paid for these procedures if Medicare had known they were medically unnecessary.

197. Following each medically unnecessary balloon dilation procedure, including the examples detailed from the patients identified above, the Defendants submitted claims for payment to Medicare, Medicaid, or TRICARE, depending on the patient's coverage, using claim Form 1500.

198. In each claim, the Defendants listed the CPT Code associated with the medically unnecessary balloon dilation procedure, the charges associated with the procedure, and the identification number of the rendering provider based on the information provided to Chesapeake Bay from Saffold.

199. In each claim the Defendants submitted to the Government, the Defendants falsely represented that the balloon dilation was medically necessary.

200. Saffold knew each claim for payment was false because he knew medical necessity was a prerequisite for payment by the Government.

201. Saffold knew these claims were not medically necessary because, as the rendering provider, Saffold knew that the patient's medical condition did not justify surgical intervention with a balloon dilation on all the claimed sinuses.

202. Saffold knew that staging these procedures did not provide any medical benefit to patients and increased their risk of harm.

203. Chesapeake Bay knew each claim for payment was false because it knew medical necessity was a prerequisite for payment by the Government.

204. Saffold and Chesapeake Bay submitted claims for medically unnecessary balloon dilation procedures to fraudulently obtain payment from Medicare, Medicaid, and TRICARE.

205. Saffold staged balloon dilation procedures to fraudulently increase reimbursement for Chesapeake Bay from Medicare, Medicaid, and TRICARE.

206. Saffold and Chesapeake Bay knew staged balloon dilation procedures were not medically necessary.

207. If the Government knew that any one of these claims were for medically unnecessary balloon dilations and/or staged procedures, the Government would have denied payment because medical necessity is a material condition of payment.

208. But for the Defendants' certification that each balloon dilation and staged procedure was medically necessary, the Government would not have paid the Defendants for the procedure.

COUNT I
False or Fraudulent Claims
31 U.S.C. §3729(a)(1)(A)

209. The Government repeats and realleges paragraphs 1 through 208 above.

210. The Defendants knowingly presented or caused to presented false or fraudulent claims for payment through Medicare, Medicaid, and TRICARE for medically unnecessary services and services that were not performed, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

211. The Defendants, through their false or fraudulent claims for medically unnecessary services and services that were not performed, caused the Government to pay the Defendants for those services, resulting in damages to the Government.

212. The Defendants are liable to the United States for civil penalties of $5,500 to $11,000, adjusted for inflation, for each false or fraudulent claim that they submitted, plus three times the amount of damages the United States sustained because of the Defendants' conduct.

COUNT II
False Statements Material to False Claims
31 U.S.C. § 3729(a)(1)(B)

213. The Government repeats and realleges paragraphs 1 through 208 above.

214. The Defendants knowingly made and used false statements material to false or fraudulent claims for payment through Medicare, Medicaid, and TRICARE for medically unnecessary services and services that were not performed, in violation of the False Claims Act, § 3729(a)(1)(B).

215. The Defendants, through their false statements material to false or fraudulent claims for medically unnecessary services and services that were not performed, caused the Government to pay the Defendants for those services, resulting in damages to the Government.

216. The Defendants are liable to the United States for civil penalties of $5,500 to $11,000, adjusted for inflation, for each false statement they made or used that was material to a false or fraudulent claim, plus three times the amount of damages the United States sustained because of the Defendants' conduct.

COUNT III
False or Fraudulent Claims
Va. Code § 8.01-216.3(A)(1)

217. The Government repeats and realleges paragraphs 1 through 208 above.

218. The Defendants knowingly presented or caused to presented false or fraudulent claims for payment through DMAS for medically unnecessary services and services that were not performed, in violation of the VFATA. Va. Code § 8.01-216.3(A)(1).

219. The Defendants, through their false or fraudulent claims for medically unnecessary services and services that were not performed, caused the Government to pay the Defendants for those services, resulting in damages to the Government.

COUNT IV
False Statements Material to False Claims
Va. Code § 8.01-216.3(A)(2)

220. The Government repeats and realleges paragraphs 1 through 208 above.

221. The Defendants knowingly made and used false statements material to false or fraudulent claims for payment through DMAS for medically unnecessary services and services that were not performed, in violation of the VFATA. Va. Code § 8.01-216.3(A)(2).

222. The Defendants, through their false statements material to false or fraudulent claims for medically unnecessary services and services that were not performed, caused the Government to pay the Defendants for those services, resulting in damages to the Government.

223. The Defendants are liable to the Commonwealth for civil penalties of $5,500 to $11,000, adjusted for inflation, for each false statement they made or used that was material to a false or fraudulent claim, plus three times the amount of damages the Commonwealth sustained because of the Defendants' conduct.

COUNT V
Common-law Fraud

224. The Government repeats and realleges paragraphs 1 through 208 above.

225. The Defendants knowingly or intentionally made false representations of material fact to Medicare, Medicaid, and TRICARE with the intent to mislead the Government about medically unnecessary services and services that were not performed.

226. The Government reasonably relied on the Defendants' false representations about medically unnecessary services and services that were not performed, which caused the Government to pay claims for those services and resulted in damages to the Government.

COUNT VI
Unjust Enrichment

227. The Government repeats and realleges paragraphs 1 through 208 above.

228. The Defendants submitted claims for services to Medicare, Medicaid, and TRICARE, even though the services were not medically necessary or performed.

229. Based on the Defendants' claims, the Government conferred a benefit upon the Defendants by paying their claims for services that were not medically necessary or were not performed.

230. The Defendants knew the Government paid the Defendants for services that were not medically necessary or were not performed.

231. The Defendants accepted and retained these payments from the Government.

232. It was inequitable for the Defendants to retain these payments because the Government made the payments in exchange for services that were not medically necessary or performed.

COUNT VII
Payment by Mistake of Fact

233. The Government repeats and realleges paragraphs 1 through 208 above.

234. The Government mistakenly paid the Defendants' claims for services not performed and medically unnecessary services to Medicare, Medicaid, and TRICARE.

235. The Defendants are not entitled to the money that the Government mistakenly paid the Defendants for services not performed and medically unnecessary.

236. The Defendants cannot in good conscience retain the money that the Government mistakenly paid the Defendants for services not performed and medically unnecessary.

PRAYER FOR RELIEF

WHEREFORE, the United States and the Commonwealth of Virginia respectfully pray that:

a. The actions of the Defendants be adjudged and decreed to be unlawful and in violation of the False Claims Act, Virginia Fraud Against Taxpayers Act, and the common-law theories of fraud, unjust enrichment, and payment by mistake;

b. The United States and Commonwealth of Virginia recover treble damages determined to have been sustained by it pursuant to 31 U.S.C. § 3729(a) and Va. Code § 8.01-216.3, and judgment be entered against the Defendants jointly and severally in favor of the United States and Commonwealth of Virginia;

c. The Defendants be ordered to pay civil penalties pursuant to § 3729(a)(3) and Va. Code § 8.01-216.3(A) for each false claim or false statement;

d. The United States and Commonwealth of Virginia be awarded its costs and its expenses of this action pursuant to § 3729(a)(3) and Va. Code § 8.01-216.3(A);

e. In the alternative, the Defendants be ordered to return to the United States and Commonwealth of Virginia the amount of the payments Defendants were not entitled to receive based on the common-law theories of fraud, unjust enrichment, and payment by mistake of fact; and

f. That the United States and Commonwealth of Virginia be granted such other and further relief as the Court deems just, equitable and proper.

JURY TRIAL DEMAND

Under Federal Rule of Civil Procedure 38 and Local Civil Rule 38, the United States and Commonwealth of Virginia demand a trial by jury on any and all issues so triable.

Dated: March 15, 2024

Respectfully submitted,

JESSICA D. ABER

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